# Abstract 137

## LONG-TERM CLINICAL EVALUATION OF RETINITIS PIGMENTOSA (RP) PATIENTS IMPLANTED WITH A NOVEL EPIRETINAL PROSTHETIC DEVICE – INTERIM RESULTS

**Oral**

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**Purpose:**

A novel autonomous infrared powered epiretinal prosthetic device with intra-retinal electrodes, the NR600, has been implanted in end-stage RP patients as part of an ongoing multi-center study. The study objectives were to demonstrate safety of the NR600 System and to evaluate the performance of the device in providing visual perception

**Methods:**

The Implant is delivered into the eye through a limbal incision and is fixed to the ciliary sulcus. Once secured, the helical structure holding the device is released and the implant is guided to the macula. Post 2-4 weeks recovery, the device is activated using infrared Glasses. Stimulation is uniquely optimized per patient, followed by perception training at the clinic and at patient's home environment. The primary safety endpoint was defined as the rate and severity of SAEs and the performance endpoints include grating acuity, object localization, quality of life questionnaires and Activities of Daily Living tests.

**Results:**

Nine implanted patients, mean age 66.6±8.0 years. All tolerated the procedure well, demonstrating good and fast recovery (follow-up time 14.6 ±10.2 months). The eyes remained clear, the implant system free of tissue debris and no retinal detachments or subretinal hemorrhages were observed. Two patients experienced possibly procedure/device related SAEs (visual hallucinations followed by psychological decompensation; elevated IOP that required IOL repositioning). Stimulation thresholds were typically low, 6.5±2.5μA across all patients, supporting the concept of ultra-low retinal activation with penetrating electrodes. The NR600 system enabled otherwise severely visually impaired patients- figure identification, object discrimination and good orientation and mobility abilities.

**Conclusions:**

The interim results of the study establish safety of the NR600 prosthesis and positive efficacy for otherwise blind patients. It demonstrates that the NR600 can be implanted chronically in humans, the long-term safety results are acceptable, and that the stimulation of the retina can elicit visual percepts.